IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

WARREN WARD

Group Art Unit: 1595

Examiner: Tigabu Kassa

Serial No.: 10/595,033

Filed: January 4, 2006

For: COMPOSITIONS COMPRISING COMPONENTS COATED WITH A LIQUID IMPERMEABLE BUT GAS PERMEABLE LAYER, USE THEREOF FOR TREATING CUTANEOUS AND OTHER EXOCRINE GLAND DISEASES

Attorney Docket No.: WAW 0101 PUSA

REPLY BRIEF UNDER 37 C.F.R. § 41.41

Mail Stop Appeal Brief - Patents
Commissioner for Patents
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

For the above-identified application, this Reply Brief is in response to the Examiner's Answer mailed on March 9, 2011, hereinafter "the Examiner's Answer", which is further in response to Appellant's Appeal Brief of December 9, 2010, hereinafter "Appellant's Appeal Brief."

Claim rejections are maintained for reasons substantially similar, if not word-for-word-identical, to the reasons previously asserted. *See* page 3-7 of the Examiner's Answer in view of pages 2-10 of the prior Office Action of June 23, 2010. Appellant believes the claim rejections have been well addressed via Appellant's Appeal Brief and relevant contents thereof are not reproduced herein for brevity. However, Appellant wishes to submit the following to respond to the additional comments raised in the Examiner's Answer.

As evidenced in the Summary and pages 8, 11-12 and 22 of the Examiner's Answer, the Examiner continues to require, for the purpose of establishing utility under 35 U.S.C. §101, a credible "scientifically accepted" utility. The utility requirement pursuant to 35 U.S.C. §101 does not require a utility that must be scientifically accepted. The Examiner's asserted standard is unsubstantiated, for which the Examiner is requested to provide authority. Rather, in therapeutic and pharmacological arts, previous lack of success or understanding as to how a certain disease or condition can be treated, should not, standing alone, serve as a basis for challenging the asserted utility under 35 U.S.C. §101. *See* also MPEP §2107.02 and §2107.03.

Unless and until the Examiner has produced authority for the credible "scientifically accepted" utility requirement under 35 U.S.C. §101 and has clarified what "scientifically accepted" concept really amounts to, Appellant neither has the burden nor is equipped to comment on whether the claimed invention is "scientifically accepted."

Appellant has established that the claimed invention can be used to deliver certain therapeutic effects. *See* pages 6, 7 and 17 of Appellant's Appeal Brief. The mere fact that this asserted utility may be difficult to comprehend does not support, by itself, the claimed invention must lack utility. Nor does it entitle the Examiner to base the lack of utility claim rejection on an unsubstantiated standard of requiring a credible scientifically acceptable utility.

On page 12 of the Examiner's Answer, the Examiner seems to have introduced a new concept "the laws of pharmacology". Appellant respectfully requests that the Examiner produce scientific and legal authority for this concept and what this new concept entails. If the

Examiner believes that a composition must dissolve to have any effect, an example to the contrary is readily available. For instance, Radiogardase (R) is an FDA approved pharmaceutical formulation of Prussian Blue, wherein it is stated on the package insert "Prussian blue insoluble ferric (III) hexacyanoferrates (II), after oral ingestion is not absorbed through the intact gastrointestinal wall. Its clearance from the body depends on the gastrointestinal tract transit time." *See* Exhibit 1.[1]

Regarding Appellant's comments stated on page 9-10 of Appellant's Appeal Brief, the Examiner applies a new reference *Zhou* et al. and argues that *Zhou* et al. evidences that metformin "has a bind AMPK". *See* page 17 of the Examiner's Answer. This statement scientifically wrong, unfortunately. *Zhou* et al. discloses that metformin activates AMPK, an intracellular signaling molecule. As well understood in the scientific community, activation does not necessarily require binding and binding does not necessarily induce activation. Even if it could be argued as true, the argument that *Zhou* et al. discloses metformin's binding to AMPK is also largely irrelevant to the instant issue of utility under 35 U.S.C. §101. Pages 9-10 of Appellant's Appeal Brief, in referencing metformin, are provided to evidence that a molecule does not always have to bind to a receptor and may still have some therapeutic effect.

The Examiner acknowledges that making the claimed invention is sufficiently enabled. *See* pages 19 to 20 of the Examiner's Answer. The Examiner also acknowledges that the claim scope is sufficiently narrow and that the use of the claimed invention as a medical device is sufficiently enabled. *See* pages 19 and 21 of the Examiner's Answer in view of page 17 of the Appellant's Appeal Brief. In view of this, Appellant respectfully submit that the use of the claimed invention is also sufficiently enabled.

Contrary to what is asserted on page 15 of the Examiner's Answer, the fact of Appellant's claims recite the preparation in compositional form does not exclude its use in and as a device. This is particularly true at least because the pending claims are presented as "open-ended" via the phrase of "comprising". Conversely, the fact that the claimed composition can be used as a medical device does not necessarily limit that the claimed composition must be a

[1] Submitting Exhibit 1 is to address Examiner's new arguments not previously presented.

medical device, contrary to the Examiner's assertion stated on page 21 of the Examiner's Answer. Examples readily exist to show that compositional substances can be directly used as devices, according to the Food and Drug Administration (FDA). For instance, Exhibit 2[2] submitted herewith evidences gel compositions applicable as therapeutic devices.

Contrary to the Examiner's assertion on page 21 of the Examiner's Answer, the rejection of claims 7-11, 24-28, 30-33 and 35-37 under 35 U.S.C. §112, second paragraph, as being indefinite, is addressed through the section B "Claim Rejections under 35 U.S.C. §112" with particular reference to page 13 of the Appeal Brief.

Please charge any additional fees or credit any overpayment in connection with this filing to our Deposit Account No. 02-3978.

Respectfully submitted,

WARREN WARD

By /Junqi Hang/
Junqi Hang
Reg. No. 54,615
Attorney for Appellant

Date: April 28, 2011
BROOKS KUSHMAN P.C.
1000 Town Center, 22nd Floor
Southfield, MI 48075-1238
Phone: 248-358-4400
Fax: 248-358-3351

[2] Submitting Exhibit 2 is to address Examiner's new arguments not previously presented.

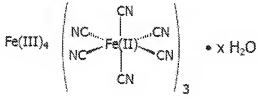
Exhibit 1

RADIOGARDASE® (PRUSSIAN BLUE INSOLUBLE CAPSULES) PACKAGE INSERT

For Oral Administration

DESCRIPTION

Prussian blue insoluble capsules contain insoluble ferric hexacyanoferrate(II), with an empirical formula of $Fe_4[Fe(CN)_6]_3$ and a molecular weight of 859.3 Daltons. It is provided as 0.5 gram of Prussian blue powder in gelatin capsules with 0 · 38 mg of microcrystalline cellulose. The powder may vary from uniformly fine, dark granules to coarse light and dark-colored granules. The structural formula for Prussian blue insoluble is shown below.



The crystal structure of Prussian blue is a cubic lattice with the FeII and FeIII atoms occupying the corners of the cube and the cyanide groups positioned on the sides.

CLINICAL PHARMACOLOGY

General

Prussian blue insoluble, ferric(III) hexacyanoferrate(II), after oral ingestion is not absorbed through the intact gastrointestinal wall. Its clearance from the body depends on the gastrointestinal tract transit time. Prussian blue insoluble acts by ion-exchange, adsorption, and mechanical trapping within the crystal structure and has a very high affinity for radioactive and non-radioactive cesium and thallium.

Prussian blue insoluble binds cesium and thallium isotopes in the gastrointestinal tract after these isotopes are ingested or excreted in the bile by the liver thereby reducing gastrointestinal reabsorption (enterohepatic circulation). In studies of rats, pigs, and dogs that were internally contaminated with cesium and thallium, the presence of the insoluble complexes in the gastrointestinal lumen, changed the primary elimination route from the kidney to the feces and increased the rate of elimination of these two contaminants.

The rate of cesium and thallium elimination was proportional to the duration and dose of Prussian blue insoluble. (See CLINICAL PHARMACOLOGY, Pharmacokinetics.) A radioactive element has a constant rate of disintegration that is reflected by its physical half-life. The rate of element elimination from the body is reflected by its biologic half-life. The combined rate of radiation disintegration and rate of element elimination is reflected by the effective half-life.

Cesium-137 (^{137}Cs) has a physical half-life of 30 years with a beta energy peak at 174.0 keV. Following entry into the blood, it is distributed uniformly through all body tissues. Approximately 10% of cesium is eliminated rapidly with a biological half-life of 2 days, and 90% is eliminated more slowly, with a biological half-life of 110 days. Less than 1% of the cesium was retained with a longer biological half-life of about 500 days. Cesium follows the movement of potassium and is excreted into the intestine, reabsorbed from the gut into the blood, then to the bile, where it is excreted again into the gut (enterohepatic circulation). Without Prussian blue insoluble treatment, ~80% of cesium is excreted through the kidneys and ~20% in the feces. Because of

03.21.2011
Ein Medikament gegen Cäsium

02.11.2011
U.S. Counterterror Chief: "Dirty Bomb" as Much a Risk as Biological Weapon

02.03.2011
MI5 Foil 'Dirty Bomb' Plot

Information for...
Healthcare Professionals
Communities
First Responders
Corporations

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Exhibit 2

Medical Devices

Gel One™ - P080020

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval

Product Name: Gel One™
PMA Applicant: Seikagaku Corporation
Address: 6-1, Marunouchi 1-chome, Chiyoda-ku, Tokyo 100-0005, Japan
Approval Date: March 22, 2011

Approval Letter: http://www.accessdata.fda.gov/ cdrh_docs/pdf8/p080020a.pdf[1]

What is it? Gel One™ is a sterile, transparent and viscoelastic gel composed of one percent hyaluronate hydrogel produced from chicken combs, in a phosphate-buffered saline solution. Gel One™ is a single treatment regimen.

How does it work? Gel One™ is a viscosupplementation[2] device, which is injected directly into the space of the knee joint.

When is it used? Gel One™ is indicated for the treatment of pain in osteoarthritis[3] of the knee in patients who have failed to respond adequately to conservative non-medicinal (non-pharmacologic) therapy and simple pain medicines (analgesics), such as acetaminophen.

What will it accomplish? Gel One™ is designed as a single injection treatment to reduce pain associated with osteoarthritis of the knee for up to 13 weeks. Side effects may include pain in the knee at the injection site, stiffness, fluid, swelling or warmth in or around the knee, changes in the way that you walk, such as limping.

When should it not be used?

- Do not administer Gel One™ to patients with a known allergy (hypersensitivity) to Gel One™ or to sodium hyaluronate preparation.
- Do not inject Gel One™ in the knees of patients with infections or skin diseases in the area of the injection site.

Additional information : Summary of Safety and Effectiveness and labeling[4] are available online.

Links on this page:

1. http://www.accessdata.fda.gov/cdrh_docs/pdf8/p080020a.pdf
2. http://orthoinfo.aaos.org/topic.cfm?topic=A00217
3. http://www.nlm.nih.gov/medlineplus/osteoarthritis.html
4. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=p080020